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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,823	06/15/2001	Lynn D. Crawford	033297-005	9229
7590	07/22/2004			EXAMINER ODLAND, KATHRYN P
T. Gene Dillahunty BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404			ART UNIT 3743	PAPER NUMBER

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/882,823	CRAWFORD ET AL.
	Examiner	Art Unit
	Kathryn Odland	3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 May 2001.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 6,8,14 and 20 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5,7,9-13 and 15-19 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 14 November 2001 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/01, 1/02, 2/02</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 6, 8, 14 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 29, 2004. Dependent claims may be rejoined pending an allowable generic claim.
2. Applicant's election with traverse of the election/restriction in the reply filed on May 29, 2004 is acknowledged. The traversal is on the ground(s) that the inventions are distinct and examination of the claims cause undue burden on the examiner. This is not found persuasive because clearly the different embodiments disclosed are different and distinct and would cause undue burden in the search.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference character(s) mentioned in the description: elements 123 and 169. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by

the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to because there are two different parts labeled 162. Perhaps one of the elements labeled 162 was intended to be referenced as 169. Further, element 158 has been designated both "plug" and "closed or blind end." Each element should only have one consistent label. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Applicant is advised to carefully review the drawings for any other errors.

Specification

5. The disclosure is objected to because of the following informalities: there appear to be typographical errors on the last line of page five: "an medical device" and "an balloon disposed." Applicant is advised to carefully review the specification for any other errors.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 3 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 3 and 11 recite, "at least part of the proximal end portion of the **elongated body** has an outer cross-dimension less than an outer cross-dimension of the distal end portion of the **elongated body**. Any art rejection is as best understood. It is possible that it was intended that the elongated body has an outer cross-dimension less than an outer cross-dimension of the distal end portion of the valve body.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-5, 7, 9-13 and 15-16 are rejected under 35 U.S.C. 102(a and/or e) as being anticipated by Zadno-Azizi et al. in US Patent No. 6,355,014.

Regarding claim 1, Zadno-Azizi et al. disclose a medical device for vessel occlusion, the medical device having an elongated body (500, 600) having a distal end portion, a proximal end portion (512, 612), and a lumen (540, etc.) disposed therethrough. A balloon is disposed at the distal end portion of the elongated body, the balloon in fluid communication with the lumen, as recited in column 15. An opening (522, 622/522, 622) is defined at the proximal end portion of the elongated body, the opening is in fluid communication with the balloon via the lumen and a valve body (550, 650) is moveably disposed at the proximal end portion of the elongated body, as seen in figures 12 and 13. The valve body is movable between a closed position and an open position, the valve body configured to engage a surface of the elongated body, distal to the opening, to seal the opening when the valve body is in the closed position, as recited in columns 15-16.

Regarding claim 2, Zadno-Azizi et al. disclose that as applied to claim 1, as well as, a surface (of the elongated body) that is engaged by the valve body when in the closed position is an outer surface of the elongated body. The proximal end of element (500, 600) will contact the inner surface of element (550, 650) as well as touch the end (562).

Regarding claims 3 and 11, Zadno-Azizi et al. disclose that as applied to claims 1 and 10, as well as, at least part of the proximal end portion of the elongated body has an outer cross-dimension less than an outer cross-dimension of the distal end portion of the elongated body/valve body, as seen in figure 13.

Regarding claims 4 and 12, Zadno-Azizi et al. disclose that as applied to claims 3 and 11, as well as, a valve body having a side wall (568, 688 with 562, etc.) having a cavity defined therein to receive the proximal end portion of the elongated body, the valve body having an outer surface substantially flush with an outer surface of the distal end portion of the elongated body when in the closed position, as recited in columns 15-16 and seen in figures 12 and 13.

Regarding claim 5, Zadno-Azizi et al. disclose that as applied to claim 1, as well as, an opening (522, 622) that is defined in a side wall of the proximal end portion of the elongated body, as seen in figures 12 and 13.

Regarding claims 7 and 13, Zadno-Azizi et al. disclose that as applied to claims 1 and 10, as well as, a valve body and elongated body that are configured for mating engagement to prevent inadvertent movement of the valve body at least when in the closed position.

Regarding claims 9 and 15, Zadno-Azizi et al. disclose that as applied to claims 1 and 10, as well as, a valve body that is moveable in an axial and rotational direction relative to the elongated body, as recited in column 15-16 and seen in figures 12 and 13.

Regarding claim 10, Zadno-Azizi et al. disclose a medical device for vessel occlusion, the medical device having an elongated body (500, 600) having a distal end portion, a proximal end portion (512, 612), and a lumen (540, etc.) disposed therethrough. A balloon is disposed at the distal end portion of the elongated body, the balloon in fluid communication with the lumen, as recited in column 15, lines 1-10. An opening (522, 622/523, 623) is defined at the proximal end portion of the elongated body, the opening being in fluid communication with the balloon via the lumen and a valve body (550, 650) is moveably disposed at the proximal end portion of the elongated body, the valve body is movable between a closed position and an open position and configured to engage an outer surface of the elongated body to seal the opening when the valve body is in the closed position, as recited in columns 15-16 and seen in figures 12 and 13.

Regarding claim 16, Zadno-Azizi discloses that as applied to claim 10, as well as, an elongated body that is constructed of Nitinol, as recited in columns 6-7.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
12. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zadno-Azizi et al. in US Patent No. 6,355,014.

Regarding claims 19-19, Zadno-Azizi et al. disclose that as applied to claim 10. However, Zadno-Azizi et al. do not explicitly recite a proximal end of the elongated body having a diameter less than the distal end, wherein the elongated body further includes a step adjacent to the proximal end of the elongated body wherein the step transitions the elongated body between the distal diameter and the proximal diameter and a valve body that is in a closed position the valve body sealingly engages the step. On the other hand, it would be obvious to one with ordinary skill in the art to modify the invention of Zadno-Azizi et al. to include a proximal end of the elongated body having a diameter less than the distal end, wherein the elongated body further includes a step adjacent to the proximal end of the elongated body wherein the step transitions the elongated body between the distal diameter and the proximal diameter and a valve body that is in a closed position the valve body sealingly engages the step, as an obvious equivalent and alternative.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US Patent No. 6,458,096 and GB 080 496.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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